Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

# General

## Guideline Title

ACR Appropriateness Criteria® soft-tissue masses.

## Bibliographic Source(s)

Kransdorf MJ, Murphey MD, Wessell DE, Cassidy RC, Czuczman GJ, Demertzis JL, Lenchik L, Motamedi K, Pierce JL, Sharma A, Walker EA, Yung EY, Beaman FD, Expert Panel on Musculoskeletal Imaging. ACR Appropriateness CriteriaÂ® soft-tissue masses. Reston (VA): American College of Radiology (ACR); 2017. 10 p. [43 references]

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Zoga AC, Weissman BN, Kransdorf MJ, Adler R, Appel M, Bancroft LW, Bruno MA, Fries IB, Morrison WB, Mosher TJ, Palestro CJ, Roberts CC, Tuite MJ, Ward RJ, Expert Panel on Musculoskeletal Imaging. ACR Appropriateness Criteria® soft-tissue masses. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 8 p. [31 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

# NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

| Assessment | Standard of Trustworthiness |
|---|---|
| YES | Disclosure of Guideline Funding Source |
| | Disclosure and Management of Financial Conflict of Interests |
| | |

| | |
|---|---|
| | Guideline Development Group Composition |
| YES | Multidisciplinary Group |
| YES | Methodologist Involvement |
| ▮▯▯▯▯ | Patient and Public Perspectives |
| | Use of a Systematic Review of Evidence |
| ▮▮▮▮▮ | Search Strategy |
| ▮▮▮▯▯ | Study Selection |
| ▮▮▮▮▯ | Synthesis of Evidence |
| | Evidence Foundations for and Rating Strength of Recommendations |
| ▮▮▯▯▯ | Grading the Quality or Strength of Evidence |
| ▮▮▮▮▮ | Benefits and Harms of Recommendations |
| ▮▮▮▮▮ | Evidence Summary Supporting Recommendations |
| ▮▮▮▮▯ | Rating the Strength of Recommendations |
| ▮▮▮▮▮ | Specific and Unambiguous Articulation of Recommendations |
| ▮▯▯▯▯ | External Review |
| ▮▮▮▯▯ | Updating |

# Recommendations

## Major Recommendations

ACR Appropriateness Criteria®

Soft-Tissue Masses

Variant 1: Soft-tissue mass. Superficial or palpable. Initial imaging study.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|---|---|
| X-ray area of interest | Usually Appropriate | Varies |
| US area of interest | Usually Appropriate | O |
| MRI area of interest without IV contrast | May Be Appropriate (Disagreement) | O |
| CT area of interest with IV contrast | Usually Not Appropriate | Varies |
| CT area of interest without and with IV contrast | Usually Not Appropriate | Varies |
| | | |

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|---|---|
| CT area of interest without IV contrast | Usually Not Appropriate | Varies |
| FDG-PET/CT area of interest | Usually Not Appropriate | ☢☢☢☢ |
| MRI area of interest without and with IV contrast | Usually Not Appropriate | O |

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Soft-tissue mass. Soft-tissue mass. Nonsuperficial (deep) or nonspecific clinical assessment or located in an area difficult to adequately evaluate with radiographs (flank, paraspinal region, groin, or deep soft tissues of the hands and feet). Initial imaging study.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|---|---|
| X-ray area of interest | Usually Appropriate | Varies |
| CT area of interest without and with IV contrast | May Be Appropriate (Disagreement) | Varies |
| CT area of interest without IV contrast | May Be Appropriate (Disagreement) | Varies |
| MRI area of interest without and with IV contrast | May Be Appropriate (Disagreement) | O |
| MRI area of interest without IV contrast | May Be Appropriate (Disagreement) | O |
| US area of interest | May Be Appropriate | O |
| CT area of interest with IV contrast | Usually Not Appropriate | Varies |
| FDG-PET/CT area of interest | Usually Not Appropriate | ☢☢☢☢ |

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Soft-tissue mass. Nondiagnostic initial evaluation (ultrasound and/or radiograph). Next imaging study.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|---|---|
| MRI area of interest without and with IV contrast | Usually Appropriate | O |
| MRI area of interest without IV contrast | Usually Appropriate | O |
| CT area of interest with IV contrast | May Be Appropriate (Disagreement) | Varies |
| CT area of interest without IV contrast | May Be Appropriate | Varies |
| CT area of interest without and with IV contrast | Usually Not Appropriate | Varies |
| FDG-PET/CT area of interest | Usually Not Appropriate | ☢☢☢☢ |

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 4: Soft-tissue mass. Nondiagnostic initial evaluation. Presenting with spontaneous hemorrhage or suspicion of vascular mass. Next imaging study.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|---|---|
| MRI area of interest without and with IV contrast | Usually Appropriate | O |

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|---|---|
| CT area of interest without and with IV contrast | Usually Appropriate | Varies |
| CTA area of interest with IV contrast | May Be Appropriate | Varies |
| MRA area of interest with IV contrast | May Be Appropriate | O |
| MRI area of interest without IV contrast | May Be Appropriate (Disagreement) | O |
| CT area of interest with IV contrast | May Be Appropriate | Varies |
| CT area of interest without IV contrast | May Be Appropriate | Varies |
| FDG-PET/CT area of interest | May Be Appropriate | ☢☢☢☢ |
| US area of interest | Usually Not Appropriate | O |

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 5: Soft-tissue mass. Nondiagnostic initial evaluation. Patient non–MRI compatible or with metal limiting MR evaluation. Next imaging study.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|---|---|
| CT area of interest with IV contrast | Usually Appropriate | Varies |
| CT area of interest without and with IV contrast | Usually Appropriate | Varies |
| CT area of interest without IV contrast | May Be Appropriate | Varies |
| FDG-PET/CT area of interest | May Be Appropriate | ☢☢☢☢ |

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Introduction/Background

Imaging is an integral component of the evaluation of patients with a suspected soft-tissue mass. Imaging can not only confirm the presence of a mass but can also provide essential information necessary for diagnosis, local staging, and biopsy planning. While the objectives of the evaluation have not changed, the choices available for imaging of musculoskeletal masses have evolved dramatically in recent years.

The purpose of this document is to identify the most common clinical scenarios and the most appropriate imaging for their assessment based on the current literature, and to provide general guidance for those scenarios that are not specifically addressed. This document does not address follow-up recommendations for patients with previously diagnosed masses or the appropriate approach or techniques for the imaging-guided biopsy of known masses. The former is covered by a separate ACR Appropriateness Criteria document, while the latter requires direct communication with the clinician or orthopedic oncologist supervising and coordinating patient care.

Soft-tissue sarcomas are considered to be quite rare, representing <1% of all malignancies. Consequently, there is limited level 1 evidence addressing the optimal imaging techniques for their assessment. The recommendations in this document are the result of the assessment of the available literature, combined with the experience of the members of the ACR Appropriateness Criteria Expert Panel on Musculoskeletal Imaging. Finally, we must emphasize a fundamental tenet of orthopedic oncology: if a "…practitioner, or the institution, is not equipped to perform accurate diagnostic studies or definitive operative and adjunctive treatment,… then it is in the patient's best interest to be referred to a

treatment center before performance of the biopsy."

Discussion of Procedures by Variant

*Variant 1: Soft-Tissue Mass. Superficial or Palpable. Initial Imaging Study*

The body regions covered in this clinical scenario are: neck, chest, abdomen, pelvis, humerus, elbow, forearm, wrist, hand, femur, knee, tibia, ankle, and foot.

Radiographs

There is scant literature assessing the evaluation of clinically palpable soft-tissue masses. In a study of 122 patients with lipomas, the most common soft-tissue tumor, investigators found that only 85% of lesions were correctly identified by physical examination alone.

Initial assessment of a suspected musculoskeletal soft-tissue mass begins almost invariably with radiographic evaluation, a fundamental concept that is emphasized by the American College of Radiology Appropriateness Committee. Although often considered unrewarding, a recent study of the radiographic evaluation of 454 patients with proven soft-tissue masses demonstrated positive results in 62% of cases, with calcification identified in 27% of cases, bone involvement in 22%, and intrinsic fat in 11%. Radiographs may be diagnostic of an unsuspected skeletal abnormality or deformity that may manifest as a soft-tissue mass. Specifically, radiographs may be diagnostic or highly characteristic, allowing identification of phleboliths within a hemangioma, the osteocartilaginous masses of synovial chondromatosis, or the peripherally more mature ossification of myositis ossificans, to name just a few. When nondiagnostic, radiographs may provide information on the type and scope of mineralization, the presence or absence of unsuspected foreign matter, or changes within the adjacent bone that may be helpful in determining the imaging modality for the "next study" if required. However, radiographs have limitations and may be unrewarding when a mass is small, deep-seated, nonmineralized, or in an area with complex anatomy such as the flank, paraspinal region, groin, or deep soft tissues of the hands and feet.

US

More recently, there has been increased use of ultrasound (US) as the initial diagnostic imaging method in assessment of soft-tissue masses. US has proven to be most useful when applied to evaluation of small superficial lesions, typically those superficial to the deep fascia. Accordingly, US may be useful as an initial imaging study in the setting of a suspected superficial or subcutaneous lipoma, leading to accurate identification in the majority of cases demonstrating characteristic features, such as no or minimal acoustic shadowing, no or minimal vascularity, and simple curved echogenic lines within an encapsulated mass. One study evaluated the accuracy of US in the assessment of histologically confirmed superficial soft-tissue masses. The overall sensitivity and specificity were 94.1% and 99.7%, respectively, being highest for lipoma, followed by (in decreasing order) vascular malformation, epidermoid cyst, and nerve sheath tumor. While these results highlight the accuracy of US in the assessment of superficial masses, one must remember the influence of pretest probability in statistical analysis and the fact that the overwhelming majority of superficial masses evaluated in clinical practice are benign (96% in the referenced study). While extremely useful, it is important to emphasize that when US imaging or clinical features are atypical, further imaging is required. In addition, US may be helpful in differentiating a localized mass from diffuse edema and in differentiating a solid from a cystic lesion. US is also useful for confirming fluid content of a suspected ganglion cyst (in the appropriate clinical setting), identifying fluid surrounding a tendon affected by acute tenosynovitis, and demonstrating the relationship between a mass and adjacent neurovascular structures.

MRI

Literature does not support the use of magnetic resonance imaging (MRI) as the initial examination for a soft-tissue mass. The inherent limitations of this modality, most notably in the identification of mineralization, limit its use in isolation.

CT

Computed tomography (CT) is not typically ordered for the initial evaluation of a soft-tissue mass.

FDG-PET/CT

Positron emission tomography using the tracer fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG-PET)/CT is not typically ordered for the initial evaluation of a soft-tissue mass.

*Variant 2: Soft-Tissue Mass. Nonsuperficial (Deep) or Nonspecific Clinical Assessment of Located in an Area Difficult to Adequately Evaluate with Radiographs (Flank, Paraspinal Region, Groin, or Deep Soft Tissues of the Hands and Feet). Initial Imaging Study*

The body regions covered in this clinical scenario are: neck, chest, abdomen, pelvis, humerus, elbow, forearm, wrist, hand, femur, knee, tibia, ankle, and foot.

Radiographs

As noted for Variant 1, radiographs remain the modality best suited for the initial assessment of a suspected musculoskeletal soft-tissue mass. However, radiographs have limitations and may be unrewarding when a mass is small, deep-seated, nonmineralized, or in an area with complex anatomy such as the flank, paraspinal region, groin, or deep soft tissues of the hands and feet.

US

The diagnostic accuracy of US is considerably less when lesions outside the subcutaneous tissue are included. It is also less reliable for defining deep masses in large anatomical areas. In the assessment of deep lipomas, for example, accuracy drops precipitously.

MRI

Literature does not support the use of MRI as the initial examination for a soft-tissue mass.

CT

CT can be a useful adjunct following radiographs and is particularly useful in assessment of mass mineralization in areas where the osseous anatomy is complex or obscured, and it may be appropriate as the initial or complementary imaging modality in such situations. In addition to being useful for identifying calcification, CT is also the optimal imaging method to characterize soft-tissue mineralization. It allows distinction of ossification from calcification and identification of characteristic patterns of mineralization. CT is also superior to radiography in detecting the zonal pattern of mineralization, essential to radiologic diagnosis of early myositis ossificans, a pattern that can be identified at CT, while radiographs remain nonspecific. In addition, the multiplanar capability of CT is ideally suited to depict the character of the interface between a soft-tissue mass and the adjacent osseous cortex in assessment of cortical remodeling or invasion. While there is little literature addressing the subject, the panel recognizes that distinguishing subtle calcification and enhancement may be difficult or impossible without at least some precontrast images.

FDG-PET/CT

FDG PET/CT is not typically ordered for the initial evaluation of a soft-tissue mass. The CT component associated with PET/CT is not optimal for accurate characterization of soft-tissue mineralization.

*Variant 3: Soft-Tissue Mass. Nondiagnostic Initial Evaluation (Ultrasound and/or Radiograph). Next Imaging Study*

The body regions covered in this clinical scenario are: neck, chest, abdomen, pelvis, humerus, elbow, forearm, wrist, hand, femur, knee, tibia, ankle, and foot.

CT

A multi-institutional study of 133 patients with primary soft-tissue malignancies found no statistically significant difference between MRI and contrast-enhanced CT imaging in determining tumor involvement of muscle, bone, joint, or neurovascular structures. While CT lacks the specificity afforded by MRI in many cases, it does provide appropriate staging data. CT remains an important adjunct in the evaluation of a soft-tissue mass. CT may be the study of choice in patients for whom MRI is contraindicated or not feasible due to large body habitus or pacemakers. As noted above, the panel recognizes that distinguishing subtle calcification and enhancement may be difficult or impossible without at least some precontrast images.

MRI

MRI has become the technique of choice for detecting and characterizing soft-tissue masses. Its improved soft-tissue contrast and multiple-image-plane capabilities have provided significant advantages for lesion conspicuity, intrinsic characterization, and local staging. Vascular structures can also be more easily identified and evaluated without the need for intravenous (IV) contrast agents, and neurovascular involvement is more easily defined.

Although lesions are more easily detected with MRI, its ability to differentiate benign from malignant lesions remains somewhat more controversial. Recent studies have shown that MRI can correctly diagnose approximately 50% of histologically confirmed cases using imaging and available clinical information. More significantly, greater expertise with tumor MRI has been associated with an increased accuracy in distinguishing benign and malignant soft-tissue tumors in cases in which imaging and clinical data are available. In a 2005 prospective, multi-institutional study of 548 untreated histologically confirmed soft-tissue lesions, the investigators were able to demonstrate an accuracy of 85% using consensus interpretation by two experienced radiologists. Malignancies, by virtue of their very nature and potential for autonomous growth, are generally larger and more likely to outgrow their vascular supply with subsequent infarction, necrosis, and heterogeneous signal intensity on fluid-sensitive MRIs. Consequently, the larger the mass and the greater its heterogeneity, the greater the concern for malignancy. Only 5% of benign soft-tissue tumors exceed 5 cm in diameter. Additionally, most malignancies are deep-seated lesions, whereas approximately 1% of all benign soft-tissue tumors are deep. Although these figures are based on surgical, not imaging, series, these trends are likely still valid for radiologists. Also, an increasing percentage of malignant lesions are found with increasing age.

Location is also important in predicting benign or malignant lesions. For example, in the Armed Forces Institute of Pathology series, 70% of retroperitoneal lesions (for all age groups) were malignant in comparison to 15% for the hand and wrist. Investigators performed a multivariate statistical analysis of 10 imaging parameters, individually and in combination. These researchers found that malignancy was predicted with the highest sensitivity when lesions had high signal intensity on T2-weighted images, were >33 mm in diameter, and had heterogeneous signal intensity on T1-weighted images. The signs that had the greatest specificity for malignancy included tumor necrosis, bone or neurovascular involvement, and mean diameter of >66 mm.

In general, MR contrast agents enhance the signal intensity on T1-weighted MRIs of many tumors, typically enhancing the demarcation between viable tumor and muscle, edema-like reactive change, hemorrhage, and tumor necrosis, as well as providing information on tumor vascularity. MRIs are generally useful for soft-tissue mass evaluation.

FDG-PET/CT

As a general rule, PET/CT imaging maximum standard uptake value ($SUV_{max}$) can be useful for differentiating between benign and malignant musculoskeletal masses. When combined with anatomic data provided by CT, FDG-PET/CT can be useful in distinguishing aggressive soft-tissue tumors from benign lesions. These studies, while encouraging, included a variety of lesion types, with limited numbers of individual entities. While the role of FDG-PET/CT is expanding, its role for the evaluation of soft-tissue tumors is not yet fully established. However, FDG-PET/CT can be a useful adjunct in many cases. One study showed that FDG-PET can be used to determine a tumor glycolytic phenotype in sarcomas, which correlates significantly with histologic grade. Fused FDG-PET/CT images can be used to plan biopsy,

targeting areas with more metabolic activity that may give higher diagnostic yield. Moreover, FDG-PET/CT is an excellent modality to detect metastatic disease and assess treatment response. FDG-PET/CT is not typically used during the initial assessment of a soft-tissue mass.

US

There are no data to recommend the use of US in the general evaluation and staging a deep soft-tissue mass.

*Variant 4: Soft-tissue Mass. Nondiagnostic Initial Evaluation. Presenting with Spontaneous Hemorrhage or Suspicion of Vascular Mass. Next Imaging Study*

The body regions covered in this clinical scenario are: neck, chest, abdomen, pelvis, humerus, elbow, forearm, wrist, hand, femur, knee, tibia, ankle, and foot.

US

There is little literature specifically addressing the distinction of hemorrhagic tumor and hematoma. Investigators reviewed 25 such cases with initial US (4 patients) and MRI (21 patients), none of which were correctly characterized as malignant. While the details of imaging are not addressed in this study, these results do serve to emphasize the potential difficulties inherent in this evaluation.

CTA

In a comparison with vascular MRI, CT angiography (CTA) with 3-D reconstruction was found to be equivalent to MRI in its ability to demonstrate neurovascular involvement and, not surprisingly, was superior to MRI in its ability to identify calcification/ossification and cortical/marrow involvement. The panel notes that CTA and CT are typically complementary studies and, as such, are usually obtained concurrently.

CT

CT remains an extremely useful technique to assess lesion vascularity. In the assessment of vascular lesions, precontrast images are especially useful in distinguishing calcification and enhancement.

MRI

Hemorrhagic soft-tissue masses present a special problem in distinguishing between hematoma and hemorrhagic neoplasm. Enhanced imaging using a subtraction technique (electronic subtraction of precontrast and postcontrast images) has been shown to be a useful technique in distinguishing hematoma and hemorrhagic sarcoma by identifying enhancing areas of tumor.

MRA

MR angiography (MRA) can be a useful adjunct to assess vascular anatomy as well as lesion vascularity. It is considered complementary to conventional MR imaging and, as such, is usually obtained concurrently.

FDG-PET/CT

It is suspected that FDG-PET/CT can be useful in the distinction of hemorrhagic tumor and hematoma by identifying the increased tumor metabolic activity.

*Variant 5: Soft-Tissue Mass. Nondiagnostic Initial Evaluation. Patient Non-MRI Compatible or with Metal Limiting MR Evaluation. Next Imaging Study*

The body regions covered in this clinical scenario are: neck, chest, abdomen, pelvis, humerus, elbow, forearm, wrist, hand, femur, knee, tibia, ankle, and foot.

CT

CT has become a useful technique for the evaluation of patients who cannot undergo MRI. In the

evaluation of suspected tumors, contrast imaging is especially useful in distinguishing vascularized from potentially necrotic regions of the tumor. Pre-contrast imaging is also important to differentiate calcification from vascular enhancement.

Dual-energy CT is a relatively new technology that has proved itself as a useful adjunct in evaluation of soft-tissue masses. Using the differences in energy attenuation of soft tissue at 80 kVp and 140 kVp, this technique has proven to be a useful method to evaluate metal implants by generating images acquired by monoenergetic high-energy quanta, reducing metal artifact. Use of this technique can significantly reduce metal artifact in the assessment of metal implants, improving the diagnostic value of imaging. Most recently, it has also shown application in the assessment of marrow edema and has been investigated in the distinction of marrow edema from intramedullary tumor invasion.

FDG-PET/CT

While FDG-PET/CT is not typically used during the initial assessment of a soft-tissue mass, it can be a useful adjunct in specific instances. As a general rule, the PET imaging $SUV_{max}$ can be useful for differentiating between benign and malignant musculoskeletal masses, and when combined with anatomic data provided by CT, it can be useful in distinguishing aggressive soft-tissue tumors from benign lesions. These studies, while encouraging, included a variety of lesion types, with limited numbers of individual entities. While the role of FDG-PET/CT is expanding, its role for the evaluation of soft-tissue tumors is not yet fully established. FDG-PET/CT can, however, be a useful adjunct in many cases. One study showed that FDG-PET can be used to determine a tumor glycolytic phenotype in sarcomas, which correlates significantly with histologic grade; PET/CT fusion images can be used to plan biopsy, targeting areas with more metabolic activity that may give higher diagnostic yield. Moreover, PET/CT is an excellent modality to detect metastatic disease and assess treatment response. FDG PET/CT is not typically used during the initial assessment of a soft-tissue mass.

Summary of Recommendations

The initial imaging study for a superficial or palpable soft-tissue mass should be radiographs. US is equally appropriate for small lesions that are superficial to the deep fascia.
For deep masses or lesions in areas difficult to evaluate radiographically (i.e., groin, paraspinal area, deep soft tissues of the hands and feet, or flank), radiographs are also usually appropriate.
If the initial evaluation of soft-tissue masses is nondiagnostic, further evaluation with MRI without and with IV contrast or MRI without IV contrast is usually appropriate.
In patients presenting with spontaneous hemorrhage or suspicion of a vascular mass, if the initial evaluation is nondiagnostic, further evaluation with either MRI without and with IV contrast or CT without and with IV contrast is usually appropriate.
If the initial evaluation of a soft-tissue mass is nondiagnostic in patients who are non–MRI compatible or who have metal limiting MRI evaluation, CT with IV contrast or CT without and with IV contrast is usually appropriate as the next imaging study.

Abbreviations

CT, computed tomography
CTA, computed tomography angiography
FDG-PET, fluorine-18-2-fluoro-2-deoxy-D-glucose positron emission tomography
MRA, magnetic resonance angiography
MRI, magnetic resonance imaging
US, ultrasound

Relative Radiation Level Designations

| Relative Radiation Level* | Adult Effective Dose Estimate Range | Pediatric Effective Dose Estimate Range |
|---|---|---|
| O | 0 mSv | 0 mSv |
| | | |

| Relative Radiation Level* | Adult Effective Dose Estimate Range | Pediatric Effective Dose Estimate Range |
| --- | --- | --- |
| ☢ | <0.1 mSv | <0.03 mSv |
| ☢☢ | 0.1-1 mSv | 0.03-0.3 mSv |
| ☢☢☢ | 1-10 mSv | 0.3-3 mSv |
| ☢☢☢☢ | 10-30 mSv | 3-10 mSv |
| ☢☢☢☢☢ | 30-100 mSv | 10-30 mSv |
| *RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies." | | |

## Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

# Scope

## Disease/Condition(s)

Soft-tissue masses

## Guideline Category

Diagnosis

Evaluation

## Clinical Specialty

Family Practice

Internal Medicine

Oncology

Radiology

## Intended Users

Advanced Practice Nurses

Health Care Providers

Hospitals

Managed Care Organizations

Physician Assistants

Physicians

Students

Utilization Management

## Guideline Objective(s)

To evaluate the appropriateness of initial imaging procedures for patients with soft-tissue masses

## Target Population

Patients with soft-tissue masses

Note: This document does not address follow-up recommendations for patients with previously diagnosed masses or the appropriate approach or techniques for the imaging-guided biopsy of known masses.

## Interventions and Practices Considered

1. X-ray, area of interest
2. Ultrasound (US), area of interest
3. Computed tomography (CT), area of interest
    - Without intravenous (IV) contrast
    - With IV contrast
    - Without and with IV contrast
4. CT angiography, area of interest with IV contrast
5. Magnetic resonance imaging (MRI), area of interest
    - Without IV contrast
    - Without and with IV contrast
6. MR angiography, area of interest with IV contrast
7. Fluorine-18-2-fluoro-2-deoxy-D-glucose positron emission tomography (FDG-PET)/CT, area of interest

## Major Outcomes Considered

- Utility of imaging procedures in evaluation of soft-tissue masses
- Sensitivity and specificity of imaging procedures in evaluation of soft-tissue masses

# Methodology

## Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

Of the 30 citations in the original bibliography, 10 were retained in the final document.

A literature search was conducted in May 2015, March 2016, and July 2017 to identify additional evidence published since the *ACR Appropriateness Criteria® Soft-Tissue Masses* topic was finalized. Using the search strategies described in the literature search companion (see the "Availability of Companion Documents" field), 7,222 unique articles were found. Twenty-four articles were added to the bibliography. The remaining articles were not used due to either poor study design, the articles were not relevant or generalizable to the topic, or the results were unclear or biased.

The author added 6 citations from bibliographies, Web sites, or books that were not found in the literature searches.

Three citations are supporting documents that were added by staff.

See also the American College of Radiology (ACR) Appropriateness Criteria® literature search process document (see the "Availability of Companion Documents" field) for further information.

## Number of Source Documents

Of the 30 citations in the original bibliography, 10 were retained in the final document. The literature searches conducted in May 2015, March 2016, and July 2017 found 24 articles that were added to the bibliography. The author added six citations from bibliographies, Web sites, or books that were not found in the literature searches. Three citations are supporting documents that were added by staff.

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Definitions of Study Quality Categories

Category 1 - The study is well-designed and accounts for common biases.

Category 2 - The study is moderately well-designed and accounts for most common biases.

Category 3 - The study has important study design limitations.

Category 4 - The study or source is not useful as primary evidence. The article may not be a clinical study, the study design is invalid, or conclusions are based on expert consensus.

> The study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description);
>
> *Or*
>
> The study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence;
>
> *Or*
>
> The study is an expert opinion or consensus document.

Category M - Meta-analysis studies are not rated for study quality using the study element method because the method is designed to evaluate individual studies only. An "M" for the study quality will indicate that the study quality has not been evaluated for the meta-analysis study.

## Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

The topic author assesses the literature then drafts or revises the narrative summarizing the evidence found in the literature. American College of Radiology (ACR) staff drafts an evidence table based on the

analysis of the selected literature. These tables rate the study quality for each article included in the narrative.

The expert panel reviews the narrative, evidence table and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the variant table(s). Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

## Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

## Description of Methods Used to Formulate the Recommendations

Overview

The purpose of the rating rounds is to systematically and transparently determine the panels' recommendations while mitigating any undue influence of one or more panel members on another individual panel member's interpretation of the evidence. The panel member's rating is determined by reviewing the evidence presented in the Summary of Literature Review and assessing the risks or harms of performing the procedure or treatment balanced with the benefits of performing the procedure or treatment. The individual panel member ratings are used to calculate the median rating, which determines the panel's rating. The assessment of the amount of deviation of individual ratings from the panel rating determines whether there is disagreement among the panel about the rating.

The process used in the rating rounds is a modified Delphi method based on the methodology described in the RAND/UCLA Appropriateness Method User Manual.

The appropriateness is rated on an ordinal scale that uses integers from 1 to 9 grouped into three categories (see the "Rating Scheme for the Strength of the Recommendations" field).

Determining the Panel's Recommendation

Ratings represent an individual's assessment of the risks and benefits of performing a specific procedure for a specific clinical scenario on an ordinal scale. The recommendation is the appropriateness category (i.e., "Usually appropriate," "May be appropriate," or "Usually not appropriate").

The appropriateness category for a procedure and clinical scenario is determined by the panel's median rating without disagreement (see below for definition of disagreement). The panel's median rating is calculated after each rating round. If there is disagreement after the second rating round, the rating category is "May be appropriate (Disagreement)" with a rating of "5" so users understand the group disagreed on the final recommendation. The actual panel median rating is documented to provide additional context.

Disagreement is defined as excessive dispersion of the individual ratings from the group (in this case, an Appropriateness Criteria [AC] panel) median as determined by comparison of the interpercentile range (IPR) and the interpercentile range adjusted for symmetry (IPRAS). In those instances when the IPR is greater than the IPRAS, there is disagreement. For a complete discussion, please refer to chapter 8 of the RAND/UCLA Appropriateness Method User Manual.

Once the final recommendations have been determined, the panel reviews the document. If two thirds of the panel feel a final recommendation is wrong (e.g., does not accurately reflect the evidence, may negatively impact patient health, has unintended consequences that may harm health care, etc.) and the process must be started again from the beginning.

For additional information on the ratings process see the Rating Round Information document (see the "Availability of Companion Documents" field).

Additional methodology documents, including a more detailed explanation of the complete topic development process and all ACR AC topics can be found on the ACR Web site (see also the "Availability of Companion Documents" field).

## Rating Scheme for the Strength of the Recommendations

Appropriateness Category Names and Definitions

| Appropriateness Category Name | Appropriateness Rating | Appropriateness Category Definition |
|---|---|---|
| Usually Appropriate | 7, 8, or 9 | The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients. |
| May Be Appropriate | 4, 5, or 6 | The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal. |
| May Be Appropriate (Disagreement) | 5 | The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned. |
| Usually Not Appropriate | 1, 2, or 3 | The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable. |

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

Internal Peer Review

## Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current medical evidence literature and the application of the RAND/UCLA appropriateness method and expert panel consensus.

Summary of Evidence

Of the 43 references cited in the *ACR Appropriateness Criteria® Soft-Tissue Masses* document, 43 references are categorized as diagnostic references including 4 good-quality studies, and 14 quality studies that may have design limitations. There are 25 references that may not be useful as primary

evidence.

Although there are references that report on studies with design limitations, 4 good-quality studies provide good evidence.

# Benefits/Harms of Implementing the Guideline Recommendations

## Potential Benefits

Imaging is an integral component of the evaluation of patients with a suspected soft-tissue mass. Imaging can not only confirm the presence of a mass but can also provide essential information necessary for diagnosis, local staging, and biopsy planning.

## Potential Harms

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the American College of Radiology (ACR) Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

# Contraindications

## Contraindications

Magnetic resonance imaging (MRI) is contraindicated or not feasible in patients with large body habitus or pacemakers.

# Qualifying Statements

## Qualifying Statements

- The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate

other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.
- ACR seeks and encourages collaboration with other organizations on the development of the ACR Appropriateness Criteria through society representation on expert panels. Participation by representatives from collaborating societies on the expert panel does not necessarily imply society endorsement of the final document.

# Implementation of the Guideline

## Description of Implementation Strategy

An implementation strategy was not provided.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Getting Better

## IOM Domain

Effectiveness

# Identifying Information and Availability

## Bibliographic Source(s)

Kransdorf MJ, Murphey MD, Wessell DE, Cassidy RC, Czuczman GJ, Demertzis JL, Lenchik L, Motamedi K, Pierce JL, Sharma A, Walker EA, Yung EY, Beaman FD, Expert Panel on Musculoskeletal Imaging. ACR Appropriateness CriteriaÂ® soft-tissue masses. Reston (VA): American College of Radiology (ACR); 2017. 10 p. [43 references]

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2017

## Guideline Developer(s)

American College of Radiology - Medical Specialty Society

## Source(s) of Funding

The funding for the process is assumed entirely by the American College of Radiology (ACR). ACR staff support the expert panels through the conduct of literature searches, acquisition of scientific articles, drafting of evidence tables, dissemination of materials for the Delphi process, collation of results, conference calls, document processing, and general assistance to the panelists.

## Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Musculoskeletal Imaging

## Composition of Group That Authored the Guideline

*Panel Members*: Mark J. Kransdorf, MD (*Principal Author and Specialty Chair*); Mark D. Murphey, MD (*Research Author*); Daniel E. Wessell, MD, PhD (*Panel Vice-chair*); R. Carter Cassidy, MD; Gregory J. Czuczman, MD; Jennifer L. Demertzis, MD; Leon Lenchik, MD; Kambiz Motamedi, MD; Jennifer L. Pierce, MD; Akash Sharma, MD, MBA; Eric A. Walker, MD, MHA; Elizabeth Ying-Kou Yung, MD; Francesca D. Beaman, MD (*Panel Chair*)

## Financial Disclosures/Conflicts of Interest

Disclosing Potential Conflicts of Interest and Management of Conflicts of Interest

An important aspect of committee operations is the disclosure and management of potential conflicts of interest. In 2016, the American College of Radiology (ACR) began an organization-wide review of its conflict of interest (COI) policies. The current ACR COI policy is available on its Web site. The Appropriateness Criteria (AC) program's COI process varies from the organization's current policy to accommodate the requirements for qualified provider-led entities as designated by the Centers for Medicare and Medicaid Services' Appropriate Use Criteria (AUC) program.

When physicians become participants in the AC program, welcome letters are sent to inform them of their panel roles and responsibilities, including a link to complete the COI form. The COI form requires disclosure of all potential conflicts of interest. ACR staff oversees the COI evaluation process, coordinating with review panels consisting of ACR staff and members, who determine when there is a conflict of interest and what action, if any, is appropriate. In addition to making the information publicly available, management may include exclusion from some topic processes, exclusion from a topic, or exclusion from the panel.

Besides potential COI disclosure, AC staff begins every committee call with the conflict of interest disclosure statement on the Web site reminding members to update their COI forms. If any updates to their COI information have not been submitted, they are instructed not to participate in discussion where an undisclosed conflict may exist.

Finally, all ACR AC are published as part of the Journal of the American College of Radiology (JACR) electronic supplement. Those who participated on the document and are listed as authors must complete the JACR process that includes completing the International Committee of Medical Journal Editors (ICMJE) COI form which is reviewed by the journal's staff/publisher.

Dr. Cassidy reports personal fees from Johnson and Johnson outside the submitted work.

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Zoga AC, Weissman BN, Kransdorf MJ, Adler R, Appel M, Bancroft LW, Bruno MA, Fries IB, Morrison WB, Mosher TJ, Palestro CJ, Roberts CC, Tuite MJ, Ward RJ, Expert Panel on Musculoskeletal Imaging. ACR Appropriateness Criteria® soft-tissue masses. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 8 p. [31 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Available from the American College of Radiology (ACR) Web site .

## Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2017. Available from the American College of Radiology (ACR) Web site .
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 2015 Feb. 1 p. Available from the ACR Web site .
- ACR Appropriateness Criteria®. Evidence table development. Reston (VA): American College of Radiology; 2015 Nov. 5 p. Available from the ACR Web site .
- ACR Appropriateness Criteria®. Topic development process. Reston (VA): American College of Radiology; 2015 Nov. 2 p. Available from the ACR Web site .
- ACR Appropriateness Criteria®. Rating round information. Reston (VA): American College of Radiology; 2017 Sep. 5 p. Available from the ACR Web site .
- ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2018. 4 p. Available from the ACR Web site .
- ACR Appropriateness Criteria®. Manual on contrast media. Reston (VA): American College of Radiology; 2017. 125 p. Available from the ACR Web site .
- ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 2017 Mar. 4 p. Available from the ACR Web site .
- ACR Appropriateness Criteria® soft-tissue masses. Evidence table. Reston (VA): American College of Radiology; 2017. 15 p. Available from the ACR Web site .
- ACR Appropriateness Criteria® soft-tissue masses. Literature search summary. Reston (VA): American College of Radiology; 2017. 2 p. Available from the ACR Web site .

## Patient Resources

None available

## NGC Status

This summary was completed by ECRI on May 6, 2001. The information was verified by the guideline developer as of June 29, 2001. This summary was updated by ECRI on March 28, 2006. This summary was updated by ECRI Institute on May 17, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Gadolinium-based contrast agents. This summary was updated by ECRI Institute on June 20, 2007 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This summary was updated by ECRI Institute on May 21, 2010. This summary was updated by ECRI Institute on January 13, 2011 following the U.S. Food and Drug Administration (FDA) advisory on

gadolinium-based contrast agents. This summary was updated by ECRI Institute on April 17, 2013. This summary was updated by ECRI Institute on June 13, 2018. The developer agreed not to review the content.

This NEATS assessment was completed by ECRI Institute on May 30, 2018.

## Copyright Statement



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